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THERAPEUTIC HYPOTHERMIA SYSTEM WITH INTRACARDIAC HEAT EXCHANGE CATHETER AND METHOD OF TREATING ACUTE MYOCARDIAL INFARCTION

FIELD OF THE INVENTION

The present invention relates generally to methods and devices for treatment of heart disease. More particularly, it relates to a therapeutic hypothermia system including a heat exchange catheter with an intracardiac heat exchanger and a method for treating acute myocardial infarction with therapeutic hypothermia.

BACKGROUND OF THE INVENTION

Heart disease is the most common cause of death in the United States and in most countries of the western world. Coronary artery disease accounts for a large proportion of the deaths due to heart disease. Coronary artery disease is a form of atherosclerosis in which lipids, cholesterol and other materials deposit in the arterial walls gradually narrowing the arterial lumen, thereby depriving the myocardial tissue downstream from the narrowing of blood flow that supplies oxygen and other critical nutrients and electrolytes. These conditions can be further exacerbated by a blockage due to thrombosis, embolization or arterial dissection at the site of the stenosis. A severe reduction or blockage of blood flow can lead to ischemia, myocardial infarction and necrosis of the myocardial tissue.

Recent research studies have indicated that, during the acute stages of myocardial infarction, more than 50%, and possibly as much as 90%, of the myocardial tissue at risk can be salvaged by hypothermic treatment. It is theorized that hypothermia halts the progression of apoptosis or programmed cell death, which causes as much tissue necrosis as the ischemia that precipitated the myocardial infarction. To date, most attempts at hypothermic treatment for acute myocardial infarction have involved global hypothermia of the patient's entire body, for example using a blood heat exchanger inserted into the patient's vena cava. While this method has shown some efficacy in initial trials, it has a number of drawbacks. In particular, the need to cool the patient's entire body with the heat exchanger slows the process and delays the therapeutic effects of hypothermia. The more quickly the patient's heart can be cooled, the more myocardial tissue can be successfully salvaged. Global hypothermia has another disadvantage in that it can trigger

shivering in the patient. A number of strategies have been devised to stop the patient from shivering, but these add to the complexity of the procedure and have additional risk associated with them. Shivering can be avoided altogether by induction of localized hypothermia of the heart or of the affected myocardium without global hypothermia. Localized hypothermia has the additional advantage that it can be achieved quickly because of the lower thermal mass of the heart compared to the patient's entire body. Rapid induction of therapeutic hypothermia gives the best chance of achieving the most myocardial salvage and therefore a better chance of a satisfactory recovery of the patient after acute myocardial infarction.

U.S. Patent 4,111,209 describes a topical hypothermia apparatus and method for treating the human body. The apparatus includes an inflatable bag that is connected to an external heat exchanger. A method is described for protecting a patient's heart while it is arrested and on cardiopulmonary bypass during open heart surgery by placing the inflatable bag into the left ventricle of the heart and inflating the bag with a circulating coolant fluid from the heat exchanger to cool the patient's myocardium. This method and apparatus are unsuitable for treating the beating heart of a patient who is experiencing an acute myocardial infarction, as the inflatable bag would occlude blood flow through the patient's left ventricle. In addition, the apparatus, as configured, would require open-chest surgical access to the heart.

What would be desirable, but heretofore unavailable, is an apparatus and method for rapid induction of therapeutic hypothermia of the heart or of the affected myocardium in a patient experiencing acute myocardial infarction. In particular, it would be desirable to provide an apparatus and method for administering therapeutic hypothermia to the beating heart of a patient without a need for surgical access to the heart and without occluding blood flow through the heart.

SUMMARY OF THE INVENTION

In keeping with the foregoing discussion, the present invention provides an apparatus and method for treating acute myocardial infarction with therapeutic hypothermia. The apparatus and method provide rapid cooling of the affected myocardium to achieve optimal myocardial salvage in a patient experiencing acute myocardial infarction.

The apparatus takes the form of a therapeutic hypothermia system including a heat exchange catheter with an intracardiac heat exchanger and an external heat exchanger connected together in a heat exchanger circuit. The heat exchange catheter has an elongated catheter shaft

configured for transluminal introduction into a heart chamber via an arterial insertion site, such as a femoral, subclavian or brachial artery or a venous insertion site, such as a femoral or jugular vein. The catheter shaft includes two fluid flow lumens, an inflow lumen and an outflow lumen, and optionally may also include a guidewire lumen. The catheter shaft has a proximal fitting configured for connecting to the heat exchanger circuit. An intracardiac heat exchanger is mounted at a distal end of the catheter shaft and in fluid communication with the inflow lumen and the outflow lumen. The intracardiac heat exchanger is configured to have an expanded position and a retracted position. In the retracted position, the intracardiac heat exchanger is compressed or wrapped around the catheter shaft for ease of insertion. Optionally, the heat exchange catheter may include an outer sheath for covering the intracardiac heat exchanger when in the retracted position. In the expanded position, the intracardiac heat exchanger expands to make thermal contact with the inside or endocardial surface of a heart chamber without occluding blood flow through the chamber.

The heat exchange catheter is connected to an external heat exchanger in a heat exchanger circuit. A pump or other pressure source circulates a heat exchange fluid through the heat exchanger circuit. Temperature controlled heat exchange fluid flows through the intracardiac heat exchanger to cool the patient's myocardium to a protective hypothermic state. The heat exchanger circuit may be an open-loop or closed-loop circuit. A temperature sensor is provided for monitoring the temperature of the heat exchange fluid. Optionally, feedback control can be used to control the temperature and/or flow rate of the heat exchange fluid to achieve optimal hypothermic protection of the affected myocardium.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1 illustrates a heat exchange catheter with a paddle-shaped intracardiac heat exchanger constructed in accordance with the present invention.

FIG 2 illustrates a variation of the heat exchange catheter with a deployment wire embedded in the periphery of the paddle-shaped intracardiac heat exchanger.

FIG 3 illustrates the distal end of the heat exchange catheter of FIG 2 with the paddle-shaped intracardiac heat exchanger inflated with a dye to show the flow path for heat exchange fluid within the heat exchanger.

FIG 4 illustrates the distal end of the heat exchange catheter of FIG 1 with a paddle-shaped intracardiac heat exchanger shown in an expanded position.

FIG 5 is a phantom view of the distal end of the heat exchange catheter of FIG 1 showing the intracardiac heat exchanger in a retracted position.

FIG 6 is a cutaway view of a patient's heart showing the heat exchange catheter of FIG 1 with the intracardiac heat exchanger in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium.

FIG 7 is a cutaway view of a patient's heart showing a variation of the heat exchange catheter of FIG 1 with a deployable wire coil for urging the intracardiac heat exchanger into thermal contact with the endocardial surface of the heart chamber.

FIG 8 illustrates the distal end of a heat exchange catheter with a conical intracardiac heat exchanger laid flat to show the pattern of flow channels.

FIG 9 is a cutaway view of a patient's heart showing the heat exchange catheter of FIG 8 with the conical intracardiac heat exchanger in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium.

FIG 10 illustrates the distal end of a heat exchange catheter with a flower-shaped intracardiac heat exchanger shown in an expanded position.

FIG 11 is a cutaway view of a patient's heart showing the heat exchange catheter of FIG 10 with the intracardiac heat exchanger in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium.

FIG 12 is a phantom view of the distal end of a variation of the heat exchange catheter of FIG 10 with a helical wire coil for expanding the intracardiac heat exchanger and urging it into thermal contact with the endocardial surface of the heart chamber.

FIG 13 is a phantom view of the distal end of a variation of the heat exchange catheter of FIG 10 with an expandable basket for expanding the intracardiac heat exchanger and urging it into thermal contact with the endocardial surface of the heart chamber.

FIG 14 shows the distal end of a variation of the heat exchange catheter of FIG 10 with a deployment wire for expanding the intracardiac heat exchanger and urging it into thermal contact with the endocardial surface of the heart chamber.

FIG 15 shows the distal end of a variation of the heat exchange catheter of FIG 10 with an inflatable ring for expanding the intracardiac heat exchanger and urging it into thermal contact with the endocardial surface of the heart chamber.

FIG 16 is a cutaway view of a patient's heart showing a heat exchange catheter with a coiled-tube intracardiac heat exchanger in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium.

FIG 17 is a cross section of a portion of the coiled-tube intracardiac heat exchanger of FIG 16 showing an optional construction of the heat exchanger tubing.

FIG 18 is a cross section of a portion of the coiled-tube intracardiac heat exchanger of FIG 16 showing another optional construction of the heat exchanger tubing.

FIG 19 shows the distal end of a heat exchange catheter with an optional pigtail catheter to facilitate crossing the patient's aortic valve with the catheter.

FIG 20 shows the distal end of a heat exchange catheter with an optional distal end closure on the outer sheath to facilitate crossing the patient's aortic valve with the catheter.

FIG 21 is a schematic diagram of a therapeutic hypothermia system with an open-loop heat exchanger circuit.

FIG 22 is a schematic diagram of a therapeutic hypothermia system with a closed-loop heat exchanger circuit.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides an apparatus and method for treating acute myocardial infarction with therapeutic hypothermia. The apparatus and method provide rapid cooling of the affected myocardium to achieve optimal myocardial salvage in a patient experiencing acute myocardial infarction. The apparatus takes the form of a therapeutic hypothermia system, shown schematically in FIGS 21 and 22, which includes a heat exchange catheter 100 with an intracardiac heat exchanger 102 and an external heat exchanger 200 connected to the heat exchange catheter 100 in a heat exchanger circuit.

FIG 1 illustrates an exemplary embodiment of a heat exchange catheter 100 for use in the therapeutic hypothermia system of the present invention. The heat exchange catheter 100 has an elongated catheter shaft 104 configured for transluminal introduction into a heart chamber via an arterial insertion site, such as a femoral, subclavian or brachial artery or a venous insertion site, such as a femoral or jugular vein. The catheter shaft 104 includes two fluid flow lumens: an inflow lumen 106 and an outflow lumen 108. The inflow lumen 106 and the outflow lumen 108 may be configured side-by-side or coaxially within the catheter shaft 104. Optionally, the catheter shaft 104 and/or the inflow lumen 106 may be thermally insulated along its length. The catheter shaft 104 has a proximal fitting 114 configured with an inflow connector 116 and an outflow connector 118 for connecting the inflow lumen 106 and the outflow lumen 108 to the heat exchanger circuit. The catheter shaft 104 may be constructed of extruded polymeric tubing

or, more preferably, of a fiber or wire braid or coil-reinforced polymeric composite tubing. The catheter shaft 104 may have an outer diameter of approximately 1 to 4 mm and a length sufficient to extend from the vascular insertion site to the patient's heart. The length of the catheter shaft 104 may be from approximately 30 to 150 cm, depending on the vascular access site chosen.

An intracardiac heat exchanger 102 is mounted at a distal end of the catheter shaft 104 and in fluid communication with the inflow lumen 106 and the outflow lumen 108. In this exemplary embodiment, the intracardiac heat exchanger 102 may be paddle-shaped or spoon-shaped when in an inflated or expanded position. The intracardiac heat exchanger 102 may be constructed, for example, by heat sealing two sheets of polymer film together with a peripheral seal 126 to create an inflatable chamber. Suitable materials for the intracardiac heat exchanger 102 include, but are not limited to, polyurethane, polyethylene, polyethylene terephthalate (PET) and metallized PET film. The paddle-shaped intracardiac heat exchanger 102 preferably has a series of internal seals 110 that create a serpentine or labyrinthine flow path or multiple parallel flow paths for the heat exchange fluid. Optionally, the heat exchange catheter 100 may include an outer sheath 112 for covering the intracardiac heat exchanger 102 when in a retracted position. Optionally, the catheter shaft 104 and/or the outer sheath 112 may include a guidewire lumen for ease in inserting and maneuvering the heat exchange catheter 100.

Optionally, the intracardiac heat exchanger 102 may be configured with a thermally conductive side for efficient heat exchange with the endocardial surface and a thermally insulated side to reduce heat exchange with the patient's blood as it passes through the heart chamber. Examples of thermally insulated materials include elastomers, natural rubber and polymer foam. A third material layer could be inflated with a gas, such as CO_2, to provide a pocket of insulation on one side of the heat exchanger. In the case of a spoon-shaped intracardiac heat exchanger 102, the convex side of the heat exchanger 102 will be the thermally conductive side and the concave side of the heat exchanger 102 will be the thermally insulated side. The intracardiac heat exchanger 102 may include radiopaque and/or sonorefletive markers to facilitate imaging the heat exchange catheter 100 by fluoroscopy and/or ultrasonic imaging. The markers may be positioned to indicate the relative positions of the thermally conductive side and the thermally insulated side of the intracardiac heat exchanger 102.

FIG 2 illustrates a variation of the heat exchange catheter 100 with a deployment wire 120 embedded in the periphery of a paddle-shaped intracardiac heat exchanger 102. The deployment wire 120 is preferably constructed of a highly resilient material, such as a

superelastic NiTi alloy or spring-tempered stainless steel, and may have a diameter of approximately 0.005 to 0.020 inches. The deployment wire 120 forms a self-expanding loop, which helps to deploy the intracardiac heat exchanger 102 and to maneuver the intracardiac heat exchanger 102 into the desired position within the patient's heart chamber. Optionally, the deployment wire 120 may extend proximally through the catheter shaft 104 to the proximal fitting 114, which provides additional control for deploying and maneuvering the intracardiac heat exchanger 102. A Touhy-Borst compression fitting or other sealing mechanism may be used to seal around the proximal ends of the deployment wire 120.

In this illustrative example of the heat exchange catheter 100, the catheter shaft 104 is constructed with an inner tube 122 and a wire coil-reinforced coaxial outer tube 124. The inflow lumen 106 extends through the inner tube 122 and the outflow lumen is defined by the annular space between the inner tube 122 and the coaxial outer tube 124. A particular advantage of this coaxial construction of the catheter shaft 104 is that it provides thermal isolation of the inflow lumen 106 from the patient's bloodstream.

FIG 3 illustrates the distal end of the heat exchange catheter 100 of FIG 2 with the paddle-shaped intracardiac heat exchanger 102 inflated with a dye to show the flow path for heat exchange fluid formed by the internal seals 110 within the heat exchanger 102. Optionally, a radiopaque dye may be added to the heat exchange fluid to facilitate visualizing the intracardiac heat exchanger 102 by fluoroscopy.

The intracardiac heat exchanger 102 is configured to have an expanded position and a retracted position. The intracardiac heat exchanger 102 is shown in the expanded position in FIG 4. In the retracted position, which is shown in FIG 5, the intracardiac heat exchanger 102 is compressed or wrapped around the distal end of the catheter shaft 104, and, optionally, may be withdrawn into the outer sheath 112, for ease of insertion.

The distal end of the heat exchange catheter 100 with the intracardiac heat exchanger 102 in the retracted position can be inserted via a vascular access site and advanced transluminally into any one of the heart chambers. By way of example, FIG 6 illustrates a cutaway view of a patient's heart showing the heat exchange catheter 100 of FIG 1 with the intracardiac heat exchanger 102 placed in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium. Once the heart chamber has been reached, the outer sheath 112 is withdrawn and the intracardiac heat exchanger 102 is expanded and maneuvered into thermal contact with the endocardial surface of the heart chamber. Thermal contact is achieved when the intracardiac heat exchanger 102 and the endocardial surface of the

heart chamber are in an effective heat transfer relationship with one another. Optimal thermal contact is achieved by direct contact between the intracardiac heat exchanger 102 and the endocardial surface of the heart chamber, however thermal contact may be achieved through radiative, conductive and/or convective heat transfer without the necessity of direct contact. The intracardiac heat exchanger 102 and the heat exchange catheter 100 are configured so that they will not interfere with ventricular outflow or the function of the aortic valve when deployed. The paddle-shaped or spoon-shaped configuration of the intracardiac heat exchanger 102 avoids occluding or significantly impeding either the blood flow through the heart chamber or the contractions of the beating heart.

FIG 7 is a cutaway view of a patient's heart showing a variation of the heat exchange catheter 100 of FIG 1 with a deployable wire coil 130 for urging the intracardiac heat exchanger 102 into thermal contact with the endocardial surface of the heart chamber. The wire coil 130 may be retracted into a straight position to facilitate transluminal insertion of the heat exchange catheter 100. Once the intracardiac heat exchanger 102 is positioned within the patient's heart chamber, the wire coil 130 may be deployed for urging the intracardiac heat exchanger 102 into thermal contact with the endocardial surface.

FIGS 8 and 9 illustrate a heat exchange catheter 100 with a generally cylindrical or conical intracardiac heat exchanger 140 mounted on the catheter shaft 104. FIG 8 illustrates the distal end of the heat exchange catheter 100 with the conical intracardiac heat exchanger 140 laid flat to show the pattern of flow channels created by the internal seals 142. The inflow lumen 106 communicates with the interior of the heat exchanger 140 through an inflow port 146 and the outflow lumen 108 communicates with the interior of the heat exchanger 140 through an outflow port 148. FIG 9 is a cutaway view of a patient's heart showing the heat exchange catheter 100 of FIG 8 with the conical intracardiac heat exchanger 140 in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium. When it is deployed within a heart chamber, the heat exchange catheter 100 has an open central portion 144 that allows unimpeded blood flow through the heart chamber. This hollow cylindrical or conical configuration also allows the intracardiac heat exchanger 140 to make thermal contact with much of the endocardial surface of the heart chamber without displacing or interfering with the function of internal structures, such as the mitral valve, papillary muscles and chordae tendineae within the left ventricle.

To assist the heat exchange catheter 100 in making thermal contact with the endocardial surface of the heart chamber, the intracardiac heat exchanger 140 may be configured so that it

has a tendency to expand to a flatter or larger diameter cylinder or cone when it is inflated and pressurized with heat exchange fluid. Alternatively or in addition, a deployment wire may be embedded into the periphery of the heat exchanger 140 to urge it into thermal contact with the endocardial surface of the heart chamber. Optionally, the cylindrical or conical intracardiac heat exchanger 140 may be configured with a thermally conductive exterior surface for efficient heat exchange with the endocardial surface and a thermally insulated interior surface to reduce heat exchange with the patient's blood as it passes through the heart chamber.

FIGS 10 and 11 show a heat exchange catheter 100 with a flower-shaped intracardiac heat exchanger 150 mounted on the catheter shaft 104. FIG 10 illustrates the distal end of the heat exchange catheter 100 with the flower-shaped intracardiac heat exchanger 150 shown in an expanded position. The intracardiac heat exchanger 150 is configured with a plurality of heat exchanger petals 152 (four in this illustrative example) surrounding an open central portion 154 that allows unimpeded blood flow through the heart chamber when the intracardiac heat exchanger 150 is deployed. Each of the heat exchanger petals 152 may be flat or spoon-shaped. Some or all of the heat exchanger petals 152 may be configured with internal flow channels for flow of the heat exchange fluid. The heat exchanger petals 152 may be connected in series or in parallel. Preferably, the proximal portion 156 of each of the heat exchanger petals 152 is narrow so that the intracardiac heat exchanger 150 will not interfere with ventricular outflow through the aortic valve when it is deployed. FIG 11 is a cutaway view of a patient's heart showing the heat exchange catheter 100 of FIG 10 with the intracardiac heat exchanger 150 in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium.

To assist the heat exchange catheter 100 in making thermal contact with the endocardial surface of the heart chamber, the intracardiac heat exchanger 150 may be configured so that the heat exchanger petals 152 have a tendency to expand outward to a larger diameter when they are inflated and pressurized with heat exchange fluid. Alternatively or in addition, a deployment wire may be embedded into the periphery of the heat exchanger petals 152 to urge them into thermal contact with the endocardial surface of the heart chamber. Optionally, the heat exchanger petals 152 of the intracardiac heat exchanger 150 may be configured with a thermally conductive exterior surface for efficient heat exchange with the endocardial surface and a thermally insulated interior surface facing the open central portion 154 to reduce heat exchange with the patient's blood as it passes through the heart chamber.

Other active or passive means may be incorporated into the heat exchange catheter 100 to assist the flower-shaped intracardiac heat exchanger 150 to make thermal contact with the endocardial surface of the heart chamber. FIG 12 is a phantom view of the distal end of a variation of the heat exchange catheter of FIG 10 with a helical wire coil 160 for expanding the intracardiac heat exchanger 150 and urging the heat exchanger petals 152 into thermal contact with the endocardial surface of the heart chamber. The helical wire coil 160 is preferably constructed of a highly resilient material, such as a superelastic NiTi alloy or spring-tempered stainless steel, and may have a diameter of approximately 0.005 to 0.020 inches. The helical wire coil 160 may be configured to passively deploy and expand the intracardiac heat exchanger 150 when it is released from the outer sheath 112 or it may be configured to be extended and retracted for actively deploying and retracting the intracardiac heat exchanger 150.

FIG 13 is a phantom view of the distal end of another variation of the heat exchange catheter 100 of FIG 10 with an expandable basket 162 for expanding the flower-shaped intracardiac heat exchanger 150 and urging the heat exchanger petals 152 into thermal contact with the endocardial surface of the heart chamber. The expandable basket 162 may be braided or woven of resilient fibers or fine wire. The expandable basket 162 may be configured to passively deploy and expand the intracardiac heat exchanger 150 when it is released from the outer sheath 112 or it may be configured to be extended and retracted for actively deploying and retracting the intracardiac heat exchanger 150.

FIG 14 shows the distal end of another variation of the heat exchange catheter 100 of FIG 10 with a deployment wire 164 for expanding the flower-shaped intracardiac heat exchanger 150 and urging the heat exchanger petals 152 into thermal contact with the endocardial surface of the heart chamber. The deployment wire 164 may be located at the distal end of the heat exchanger 150, as shown, or it may be located at a more proximal position on the heat exchanger 150. The deployment wire 164 is preferably constructed of a highly resilient material, such as a superelastic NiTi alloy or spring-tempered stainless steel, and may have a diameter of approximately 0.005 to 0.020 inches. Alternatively, the deployment wire 164 may be configured as a small diameter spring coil. The deployment wire 164 may be configured to passively deploy and expand the intracardiac heat exchanger 150 when it is released from the outer sheath 112 or it may be configured to be extended and retracted for actively deploying and retracting the intracardiac heat exchanger 150.

FIG 15 shows the distal end of a variation of the heat exchange catheter 100 of FIG 10 with an inflatable ring 166 for expanding the flower-shaped intracardiac heat exchanger 150 and

urging the heat exchanger petals 152 into thermal contact with the endocardial surface of the heart chamber. The inflatable ring 166 may be located at the distal end of the heat exchanger 150, as shown, or it may be located at a more proximal position on the heat exchanger 150. The inflatable ring 166 may be connected with the fluid flow channels within the heat exchanger petals 152 such that the inflatable ring 166 inflates whenever the heat exchanger 150 is inflated and pressurized with heat exchange fluid. Alternatively, the inflatable ring 166 may be connected with a separate inflation lumen so that the inflatable ring 166 can be inflated independently of the heat exchanger 150.

In an alternative embodiment, the heat exchanger petals 152 may be configured as a multiplicity of narrow ribs such that the ribs and the inflatable ring 166 create a cage-shaped inflatable intracardiac heat exchanger 150.

FIG 16 is a cutaway view of a patient's heart showing a heat exchange catheter 100 with a coiled-tube intracardiac heat exchanger 170 in thermal contact with the endocardial surface of the left ventricle for applying therapeutic hypothermia to the patient's myocardium. The coiled-tube intracardiac heat exchanger 170 is made up of heat exchanger tubing 172 that is preferably heat set or otherwise treated so that it will assume a helical coil configuration when it is extended from the distal end of the outer sheath 112. Alternatively or in addition, the heat exchanger tubing 172 may be constructed so that it assumes a helical coil configuration when it is inflated and pressurized with heat exchange fluid. The coiled-tube intracardiac heat exchanger 170 may also be configured so that the outer diameter of the deployed helical coil configuration can be selectively adjusted to assure good thermal contact with the endocardial surface of the heart chamber. The open configuration of the coiled-tube intracardiac heat exchanger 170 avoids occluding or significantly impeding blood flow through the heart chamber or the contractions of the beating heart.

FIG 17 is a cross section of a portion of the coiled-tube intracardiac heat exchanger 170 of FIG 16 showing an optional construction of the heat exchanger tubing 172. In this exemplary embodiment, the heat exchanger tubing 172 may be coextruded of two polymeric materials so that the tubing 172 has a high thermal conductivity side 174 facing the endocardial surface and a low thermal conductivity side 176 facing the interior of the heart chamber. The high thermal conductivity side 174 may be rendered more conductive by loading the polymer with a thermally conductive filler material. Alternatively, the high thermal conductivity side 174 may be treated post extrusion to rendered it more thermally conductive.

FIG 18 is a cross section of a portion of the coiled-tube intracardiac heat exchanger 170 of FIG 16 showing another optional construction of the heat exchanger tubing 172. In this exemplary embodiment, the heat exchanger tubing 172 may be an extruded polymer tube that has a thermally insulating material 178, for example an elastomer or polymer foam, coating the side of the tubing 172 facing the interior of the heart chamber. The heat exchanger tubing 172 may be treated to make it more thermally conductive, for example by loading the polymer with a thermally conductive filler material.

Preferably, the heat exchange catheter 100 of the present invention is configured for safe and atraumatic crossing of the aortic valve. Various features may be incorporated into the heat exchange catheter 100 to facilitate crossing the aortic valve. FIG 19 shows the distal end of a heat exchange catheter 100 with an optional pigtail catheter 190 extending from the distal end of the outer sheath 112 to facilitate crossing the patient's aortic valve with the catheter 100. Alternatively, a J-tip guidewire may be used in place of the pigtail catheter 190.

FIG 20 shows the distal end of a heat exchange catheter 100 with an optional distal end closure 192 on the outer sheath 112 to facilitate crossing the patient's aortic valve with the catheter 100. The distal end closure 192 provides a blunt rounded tip for safely crossing the aortic valve. The distal end closure 192 has a plurality of resilient end flaps 194 separated by slits 196. Once the aortic valve has been crossed, the intracardiac heat exchanger may be pushed through the distal end closure 192 to be deployed within the patient's ventricle.

Alternatively, the intracardiac heat exchanger may be partially or fully deployed within the patient's aorta to provide a blunt, atraumatic structure for safely crossing the aortic valve. This variation of the method of deployment is most suitable for more streamlined configurations of the intracardiac heat exchanger, such as the paddle-shaped or spoon-shaped intracardiac heat exchangers 100 shown in FIGS 1-7.

The heat exchange catheter 100 is part of a heat exchanger circuit, shown schematically in FIGS 21 and 22, which includes an external heat exchanger 200 and a pump 202 or other pressure source that circulates a heat exchange fluid through the heat exchanger circuit. Temperature controlled heat exchange fluid flows through the intracardiac heat exchanger 102 to cool the patient's myocardium to a protective hypothermic state. The heat exchanger circuit may be an open-loop circuit, as shown in FIG 21, or a closed-loop circuit, as shown in FIG 22. A temperature sensor 210, for example a thermocouple or thermister, is provided for monitoring the inflow temperature of the heat exchange fluid. Additional temperature sensors may be provided near the distal end of the catheter for measuring the temperature of the patient's blood

and/or myocardium. Optionally, feedback control can be used to control the temperature and/or flow rate of the heat exchange fluid to achieve optimal hypothermic protection of the affected myocardium.

Preferably, the intracardiac heat exchanger 102 is placed in thermal contact with the myocardium of the heart chamber that has been identified as ischemic or at risk for ischemic damage and/or reperfusion injury. The myocardium at risk can be identified using one or more of several diagnostic modalities, including angiography, ventriculography, thallium scintigraphy, ultrasonic imaging and electrocardiograms. In addition, the therapeutic hypothermia system of the present invention can be used in conjunction with catheter-based interventions or open heart surgery to protect myocardium potentially at risk for ischemic damage and/or for prevention of reperfusion injury. A number of catheter-based interventions that can be used in conjunction with the therapeutic hypothermia system of the present invention are described in *System and methods for catheter procedures with circulatory support in high risk patients*, U.S. patent application serial number 09/384,467, filed on August 30, 1999, which is hereby incorporated by reference in its entirety. More than one intracardiac heat exchanger 102 or heat exchange catheter 100 may be employed for administering therapeutic hypothermia simultaneously to more than one heart chamber. The therapeutic hypothermia system of the present invention may also be used in conjunction with direct coronary artery perfusion with hypothermic blood or other physiologically acceptable fluids for rapid cooling of the myocardium.

In the open-loop heat exchanger circuit shown schematically in FIG 21, the therapeutic hypothermia system includes a reservoir 204 of heat exchange fluid, such as saline solution or other physiologically acceptable fluid, a pump 202 or other pressure source and an external heat exchanger 200 connected in series to the inflow lumen 106 of the heat exchange catheter 100. The outflow lumen 108 of the heat exchange catheter 100 is connected to a sump or drain 206.

In a simplified open-loop heat exchanger circuit, the reservoir 204 may be a flexible bag filled with a heat exchange fluid, such as saline solution or other physiologically acceptable fluid, that has been precooled, for example by storing the reservoir 204 in a refrigerator, to eliminate the necessity of an external heat exchanger 200. A simple pressure source, such as an intravenous reservoir pressurization cuff, can be used in place of the pump 202. This serves to simplify the therapeutic hypothermia system, which may save setup time in an emergency situation when the patient is in acute myocardial infarction. The intracardiac heat exchanger 102 may also be prefilled with heat exchange fluid and connected to the reservoir 204 and the pressure source to facilitate setup in an emergency situation.

In the closed-loop heat exchanger circuit shown schematically in FIG 22, the therapeutic hypothermia system includes a pump 202 or other pressure source and an external heat exchanger 200 connected in series to the inflow lumen 106 of the heat exchange catheter 100. The outflow lumen 108 of the heat exchange catheter 100 is connected to an inlet of the pump 202. The heat exchanger circuit is filled with a heat exchange fluid, such as saline solution or other physiologically acceptable fluid.

In both the open-loop and closed-loop heat exchanger circuits, the external heat exchanger 200 may take any of several possible forms. In one simple form, the external heat exchanger 200 may be configured as a coil or serpentine of tubing within an ice bath or the like. Alternatively, the external heat exchanger 200 may include a temperature controlled refrigeration cycle or thermoelectric cooler for cooling and/or heating the heat exchange fluid. In another alternative, the external heat exchanger 200 may employ an endothermic or exothermic chemical reaction for cooling or heating the heat exchange fluid.

The therapeutic hypothermia system can also be used to rewarm the patient's heart after a period of therapeutic hypothermia by circulating hyperthermic or normothermic fluid through the intracardiac heat exchanger 102. The therapeutic hypothermia system can also be configured for treating the patient's heart or other organs with therapeutic hyperthermia.

While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof.